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Ethan H. Townsend
Attorney at Law
ehtownsend@mwe.com
+1 302 485 3911

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VIA E-FILING

The Honorable Colm F. Connolly
District Court of Delaware
J. Caleb Boggs Federal Building
844 N. King Street
Unit 31, Room 4124
Wilmington, DE 19801-3555

Re: *Alnylam Pharm., Inc. v. Moderna, Inc., et al.*, C.A. No. 22-335-CFC (Cons.)

Dear Chief Judge Connolly:

I write on behalf of Alnylam Pharmaceuticals Inc., regarding Moderna's Letter on its Partial Motion to dismiss, dated April 19, 2023. D.I. 78. Moderna's letter underscores that its Partial Motion to Dismiss was premature and that discovery is required.

Moderna's letter uses the Government's Statement of Interest brief filed in *Arbutus Biopharma Corp. v. Moderna, Inc.*, C.A. No. 22-252 (D. Del.) (the "*Arbutus* Matter") to effectively argue that any sales from a 2020 contract identified as C-0100 are exempt under Section 1498(a). This argument fails on several grounds.

First, when faced with similar arguments built on the Government's Statement in the *Arbutus* Matter, Judge Goldberg denied Moderna's pending Motion to Dismiss, stating: "Discovery is necessary to ensure that any application of § 1498(a) is based upon developed facts *and not solely on the Government's say-so*." *Arbutus Biopharma Corp. v. Moderna, Inc.*, C.A. No. 22-252 (D. Del.), D.I. 64 at 3 (emphasis added); *see also IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014) ("But, standing alone, a governmental grant of authorization or consent does not mean that the alleged use or manufacture is done 'for the United States' under § 1498(a)."). Moderna omits this information from its letter. As in *Arbutus*, development of the facts is required here as well.

Second, Moderna has to date not produced an unredacted version of the C-0100 Contract. It further has not produced the underlying sales data identifying what sales were pursuant to the C-0100 contract, nor other relevant documents to permit consideration of its Section 1498(a) defense.[1] Moderna is essentially asking this Court to grant its Partial Motion on its "say-so," built on a government brief in a different proceeding for unidentified sales not in evidence. That position defies all notions of fundamental fairness and due process that Rule 26 discovery provides.

Third, Rule 12(d) would require converting the Motion to a Rule 56 motion for consideration of extrinsic evidence, such as the Government's Statement, the C-0100 Contract, and sales thereunder. Rule 12(d) importantly requires that Alnylam "must be given a reasonable opportunity to present all the material that is pertinent to the motion." "The reason that a court must convert a motion to dismiss to a summary judgment motion if it considers extraneous evidence submitted by the defense is to afford the plaintiff an opportunity to respond." *Bruni v. City of Pittsburgh*, 824 F.3d 353, 360–61 (3d Cir. 2016) (quotations omitted). Either any reference to this extrinsic evidence should be excluded, or Alnylam "must be given a reasonable opportunity to present all material that is pertinent to the motion." Fed. R. Civ. P. 12(d). This Court's Scheduling Order contemplates motions for summary judgment after the close of discovery. That is when Moderna's motion should be addressed.

Finally, Moderna's admissions confirm that its whittled down motion will not meaningfully impact the case, warranting its denial. It admits all sales under the July 2022 C-0017 Contract are not exempt under Section 1498. It further does not dispute Alnylam's Opposition pointing out that Moderna's public filings show that less than 30% of its 2021 sales revenue are derived from sales to the United States Government. D.I. 14 at 6 (citing D.I. 1-1, Ex. 3 at 100; 125). With Alnylam's patent issuing in February 2022, and with the second admittedly non-exempt contract issuing in July 2022, even if the Section 1498 defense eventually has merit, it impacts a very small percentage of the unidentified sales at issue.

[1] To date, Moderna has not produced unredacted copies of any of its agreements with the U.S. Government, the underlying relevant financial and legal documents, nor has Moderna answered the Complaints. Moderna's document production to date has been limited to FDA documents, a small number of agreements, and a single set of sales figures, despite being less than six weeks away from the June 1, 2023 substantial completion date on a case pending since March 2022.

For all the reasons stated in Alnylam's opposition, its submission of subsequent authority (D.I. 57), and this letter, Alnylam requests that the Court deny Moderna's Partial Motion to Dismiss.

Respectfully,

/s/ *Ethan H. Townsend*

Ethan H. Townsend (#5813)

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cc: All Counsel of Record (via e-filing)